



**CANADIAN FERTILITY AND ANDROLOGY SOCIETY
ART LAB SPECIAL INTEREST GROUP**

**GUIDELINES FOR QUALIFICATIONS AND RESPONSIBILITIES
FOR EACH ASSISTED REPRODUCTIVE TECHNOLOGY (ART)
LABORATORY PROFESSIONAL POSITION IN CANADA**

**Prepared by the Committee on Professional Standards of the
CFAS ART Lab Special Interest Group**

**Approved by the membership of the
CFAS ART Lab Special Interest Group on June 15th, 2018
and CFAS Board of Directors on April 3rd, 2018**

BACKGROUND

This document replaces the original version, which was approved by the membership of the CFAS ART Lab Special Interest Group on November 26, 2008 and the CFAS Board of Directors on February 27, 2009. This revision was undertaken as part of the standard review process for documents, and referenced the article published by Alpha Scientists in Reproductive Medicine (“The Alpha Consensus Meeting on the professional status of the Clinical Embryologist: proceedings of an expert meeting”, *Reprod Biomed Online*, 2015; 30:451-461), which presents international recommendations for the roles and responsibilities of the Clinical Embryologist. Accordingly, some of the recommendations for qualifications in this document have been revised to meet international recommendations.

This document provides the current recommendations for the qualifications and responsibilities of Canadian ART Laboratory Professionals, who perform all laboratory aspects of in vitro fertilization procedures, as well as the preparation of sperm samples for intrauterine and intracervical insemination.

Although changes are recommended in this document, in the interests of ensuring continuity of care to infertility patients, the competency of each individual in their *current* position in clinical ART Centres **must be accepted** in relation to their formal qualifications and furthermore, it is understood that in this case vocational training and experience can be deemed to provide an equivalent level of “qualification” for a role. *For individuals entering the profession from the date of approval of this document by the Board of the Canadian Fertility and Andrology Society (CFAS)*, the CFAS ART Laboratory SIG has laid out the formal qualifications required for each position. It is agreed by the ART Lab SIG professionals (Embryologists and Andrologists) that these qualifications are the only ones that are acceptable, and that there is no equivalency with other degrees or diplomas, as no other courses currently provide the level of background knowledge required for these positions. It should be noted that in addition to formal qualifications, demonstration of further experience and technical competency is required.

As is the case at present, promotion within a laboratory to a more senior position remains at the discretion of the Laboratory Director or Scientific Director (as defined below), related to attainment of the relevant formal qualifications, experience, and demonstration of supervisory and/or other relevant management skills.

TERMINOLOGY

The terminology used for position titles in this document refer specifically to positions in an ART Laboratory. It is understood that some of these titles may have alternative uses in other laboratory specialties and / or within different provincial jurisdictions.

EXECUTIVE SUMMARY

It is the recommendation of the CFAS ART Laboratory Special Interest Group that any laboratory performing ART services, defined as handling and processing human gametes and embryos for the purpose of establishing a pregnancy, **must have** a CFAS-certified Scientific Director and/or Laboratory Director who is responsible for the laboratory activities. All other positions within the laboratory, and their specific titles, are based on the clinic/laboratory’s internal structure. This document provides recommendations with regard to the qualifications and responsibilities relevant to these positions, but does not make specific recommendations with regard to position titles.

There are many viable organizational models for the successful practice of ART in Canadian clinics. Therefore, this document does not make any specific recommendations for organizational models, beyond the requirement for a Director position, as not all roles are relevant in all clinics, due to differences

in case numbers and in the services provided. Further, the same individual could fulfil the roles of more than one level, provided that this person is certified at the highest level of their practice. However, in the interests of clarity, a sample organizational chart is presented, to provide a general overview of the relationship of (possible) positions in the ART laboratory (Figure 1).

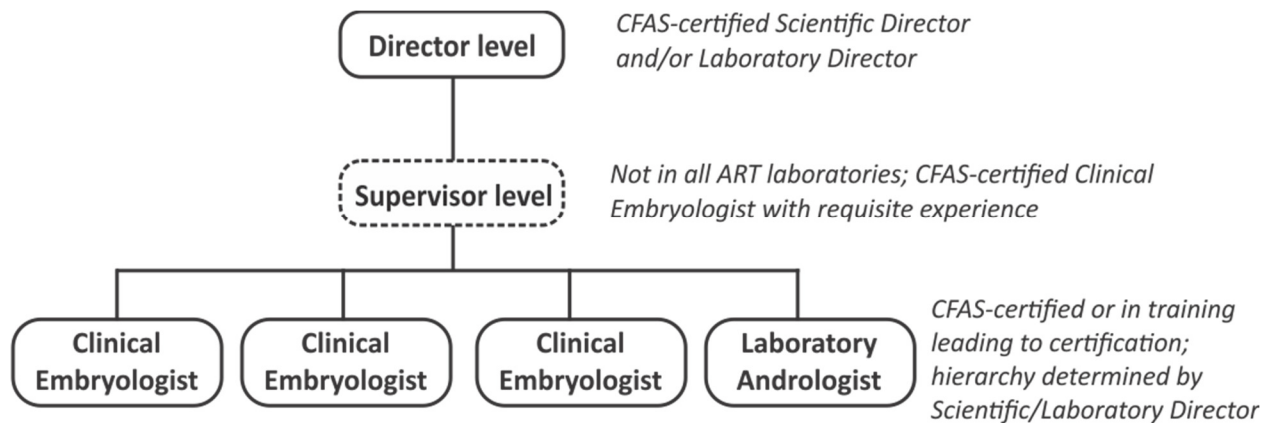


Figure 1: Sample Organizational Chart for an ART Laboratory for illustration purposes only, as there are many viable organizational models for an ART Laboratory in Canada. While the Director level should be present in all ART Laboratories, this is not necessarily the case for the Supervisor level. The type and number of positions at each level is related to the caseload and complexity of ART services provided, and so would not be expected to be consistent between ART Laboratories. Further, in some ART Laboratories, the same individual could fulfil the roles of more than one level, provided that this person is certified at the highest level of their practice.

Although this document lists the educational qualifications for each level, it is the intent that an individual would still be permitted to practice at a level which requires a lower qualification than they possess. In other words, if someone with a relevant PhD or MSc would like to enter the field, their advanced degree should not prevent them from becoming a trainee and then working their way up through the levels as their experience, competency, and certification allow.

The original version of this document referred to the need for all ART Laboratory professionals in Canada to complete a post-graduate diploma in human reproductive biology (when obtainable in Canada). The intent of this requirement was to ensure that all ART Laboratory professionals would have the same background knowledge of the field. However, since such a diploma is still not available in Canada, this requirement has not been included in this revision. Should a graduate diploma be offered in Canada in the future, this requirement should be revisited.

QUALIFICATIONS AND RESPONSIBILITIES FOR EACH ART LABORATORY PROFESSIONAL POSITION IN CANADA**Scientific Director**

Some ART Laboratories could have a Scientific Director who is responsible for the services provided by the Laboratory but who does not perform laboratory procedures. This is an executive-level position, with responsibility for developing relevant research programmes, and in that case the Scientific Director will ideally have an appointment with an affiliated University.

Responsibilities

- Developing and overseeing relevant research programmes
- Developing content and maintaining revisions of standard operating procedures
- Designing and monitoring ART Laboratory quality management programme
- Designing and monitoring ART Laboratory training programme
- Developing and implementing new ART Laboratory procedures
- Conducting performance appraisals of Laboratory employees
- Liaising with other professional groups within the clinic
- Keeping the ART Laboratory current in new developments in AHR
- Designing and monitoring the ART Laboratory data management program
- Overseeing management of ART Laboratory equipment and supplies
- Ensuring compliance of the ART Laboratory with all relevant regulations
- Membership of the ART Centre's management team
- Membership of the ART Centre's accreditation/inspection team

Qualifications***Education***

- Earned PhD in a field of biological sciences, reproductive biology, animal sciences from an accredited tertiary educational institution (with Canadian or provincial equivalency as required)

Experience and Expertise

- 5 years of full-time (or full-time equivalent) clinical ART experience
- Knowledge and expertise in:
 - Executive management skills
 - Licensing and accreditation processes
 - Quality and risk management
 - Research skills
 - Operation of an Assisted Human Reproduction Centre
- Must meet all competencies listed in the current "Competency Profiles for Assisted Reproductive Technology Laboratory Professionals in Canada", prepared by the Committee on Professional Standards of the CFAS ART Lab Special Interest Group. These are:
 - Competency Profile for an ART Lab Professional (non-supervisory position):

1. Safe Work Practices
 2. Obtaining and Processing of gametes and embryos
 3. Communication
 4. Quality and Risk Management
 5. Critical Thinking
- Competency Profile for a Supervisory or Directorial position:
1. Communicating Effectively
 2. Ethics and Integrity
 3. Inspiring a Shared Vision and Enabling the Laboratory Personnel to Act
 4. Critical Thinking
 5. Facilitating Organizational Change / Improvements
 6. Developing Others
 7. Resource Management
 8. Building Teamwork and Collaborative Partnership
 9. Achieving Results
 10. Self-Confidence, Self-Control and Personal Motivation

Laboratory Director

This position has direct responsibility for the day-to-day operation, management, organization and supervision of the laboratory staff. In addition to being responsible for the laboratory services, the Laboratory Director also performs laboratory procedures on a regular basis and is directly involved in training of new employees.

Responsibilities

- Developing content and maintaining revisions of standard operating procedures
- Performing technical laboratory procedures
- Designing and monitoring ART Laboratory quality management programme
- Designing and monitoring ART Laboratory training programme
- Developing and implementing new ART Laboratory procedures
- Evaluating and introducing new materials and procedures
- Conducting performance appraisals of laboratory employees
- Coordinating day-to-day operation of the ART Laboratory
- Liaising with other professional groups within the clinic
- Keeping the ART Laboratory current in new developments in AHR
- Designing and monitoring the ART Laboratory data management program
- Developing and overseeing relevant research programmes (in absence of Scientific Director role)
- Troubleshooting problems in the ART Laboratory
- Managing ART Laboratory equipment and supplies
- Ensuring compliance of the ART Laboratory with all relevant regulations
- Membership of the ART Centre's management team
- Membership of the ART Centre's accreditation/inspection team

Qualifications

Education

- Earned MSc or PhD in a field of biological sciences, reproductive biology, animal sciences from an accredited tertiary educational institution (with Canadian or provincial equivalency as required)

• *Experience and Expertise*

- 5 years of full-time (or full-time equivalent) technical experience in a clinical human ART Laboratory
- Supervisory experience
- Training experience
- Laboratory management
- Quality and risk management
- Knowledge of accreditation/inspection processes

and

- Must meet all competencies listed in the current version of the CFAS ART Lab SIG Competency Profile document (as per Scientific Director description)

Laboratory Supervisory Role

Depending on the ART Laboratory, the title of this role can include Laboratory Manager, Laboratory Supervisor, Lead Embryologist, or Laboratory Coordinator. This position assumes a lead role in the ART Laboratory, reporting to the Director level. The person fulfilling this role is the responsible person in the absence of the Laboratory Director.

Responsibilities

- Performing the technical procedures of a Clinical Embryologist in the ART Laboratory
- Assuming a lead role in:
 - Training and evaluation of competency of new ART Laboratory personnel
 - Day-to-day operation of the ART Laboratory
 - Troubleshooting problems in the ART Laboratory
 - Ensuring compliance with ART Laboratory SOPs

Qualifications***Education***

- Earned Baccalaureate in relevant sciences such as biological sciences, reproductive biology, animal sciences from an accredited tertiary educational institution (with Canadian or provincial equivalency as required)

Experience and Expertise

- 3 years of full-time (or full-time equivalent) technical experience in a clinical human ART Laboratory
- Training experience
- Risk management experience

and

- Must meet all competencies listed in the current version of the CFAS ART Lab SIG Competency Profile document for a supervisory position (as per Scientific Director description)

Clinical Embryologist Role

A Clinical Embryologist performs specialized technical laboratory procedures in an ART Laboratory. This role can cover a range of responsibilities, depending upon technical experience and competency, including: micromanipulation procedures on human oocytes, cryopreservation and thawing of human embryos, oocytes and sperm specimens, preparation of human sperm specimens for therapeutic procedures, performing in-vitro fertilization (IVF), and performing embryo transfers. The Clinical Embryologist may perform quality control and research bioassays on human/animal gametes/embryos and ensures proper maintenance of lab equipment and supplies. As an important team member, the Clinical Embryologist contributes to the educational activities of the Centre and the improvement of laboratory services, procedures and standards.

People in this role can be designated at different levels, such as Senior, Junior, etc, with the precise titles and responsibilities an internal decision specific to each individual ART laboratory.

Responsibilities

- Adhering to the standard operational procedures for the ART Laboratory
- Performing technical procedures on oocytes, sperm, and embryos in the ART Laboratory
- Ensuring equipment is functioning according to specifications
- Adhering to safe and ethical laboratory practices
- Working effectively within the team
- Recording observations and results accurately and fully, and placing them in a clinical context

Qualifications

Education

- Earned Bacculaureate in relevant sciences such as biological sciences, reproductive biology, animal sciences from an accredited tertiary educational institution (with Canadian or provincial equivalency as required)

Experience and Expertise

- Must meet all competencies for a non-supervisory position listed in the current “Competency Profiles for Assisted Reproductive Technology Laboratory Professionals in Canada”, prepared by the Committee on Professional Standards of the CFAS ART Lab Special Interest Group. These are:
 1. Safe work practices
 2. Obtaining and processing of gametes and embryos
 3. Communication
 4. Quality and risk management
 5. Critical thinking

Laboratory Andrologist Role

Some ART programmes, or specialized IUI/donor sperm programmes, have dedicated ART Andrology Laboratory staff members who do not have embryology responsibilities. For the purposes of this document, a person who provides specialized andrology services in the ART Laboratory is designated as a Laboratory Andrologist.

These specialized services can include: quality control and research assays on human sperm specimens; preparation of human sperm specimens for therapeutic procedures; and cryopreservation of human sperm specimens. A Laboratory Andrologist is also responsible for maintaining an accurate inventory of cryopreserved sperm specimens, and contributes to the ongoing improvement of laboratory services, procedures, and standards.

Responsibilities

- Adhering to the standard operational procedures for the ART Laboratory
- Performing technical procedures on sperm specimens to be used for ART procedures
- Ensuring equipment is functioning according to specifications
- Adhering to safe and ethical laboratory practices
- Working effectively within the team
- Recording observations and results accurately and fully

Qualifications

Education

- Earned Bacculaureate in relevant sciences such as biological sciences, reproductive biology, animal sciences from an accredited tertiary educational institution (with Canadian or provincial equivalency as required)

Experience and Expertise

- Must meet all competencies* for a non-supervisory position listed in the current “Competency Profiles for Assisted Reproductive Technology Laboratory Professionals in Canada”, prepared by the Committee on Professional Standards of the CFAS ART Lab Special Interest Group. These are:
 1. Safe work practices
 2. Obtaining and processing of gametes and embryos
 3. Communication
 4. Quality and risk management
 5. Critical thinking

* There is no requirement for a Laboratory Andrologist to meet any aspects of these competencies dealing specifically with oocytes and/or embryos

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